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CONFIRMATION NO. ATTORNEY DOCKET NO. FIRST NAMED INVENTOR FILING DATE APPLICATION NO. 03-003 (ANSI01-00015) 8284 Michael P. Schrom 07/29/2003 10/630,233 EXAMINER 12/02/2004 36029 7590 BOCKELMAN, MARK DOCKET CLERK, DM/ANSI PAPER NUMBER P.O. BOX 802432 ART UNIT DALLAS, TX 75380 3762

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	AItAla Na	Applicant(s)	-
	Application No.		W C
	10/630,233	SCHROM ET AL.	
Office Action Summary	Examiner	Art Unit	
	Mark W Bockelman	3762	day
The MAILING DATE of this communication Period for Reply			aaress
A SHORTENED STATUTORY PERIOD FOR RETHE MAILING DATE OF THIS COMMUNICATION - Extensions of time may be available under the provisions of 37 CF after SIX (6) MONTHS from the mailing date of this communication - If the period for reply specified above is less than thirty (30) days, - If NO period for reply is specified above, the maximum statutory properties of the period for reply within the set or extended period for reply will, by some any reply received by the Office later than three months after the rearned patent term adjustment. See 37 CFR 1.704(b).	JN. R 1.136(a). In no event, however, n. a reply within the statutory minimur eriod will apply and will expire SIX(may a reply be timely filed n of thirty (30) days will be considered time 6) MONTHS from the mailing date of this ome ABANDONED (35 U.S.C. § 133).	ely. communication.
Status			
1) Responsive to communication(s) filed on	<u>20 September 2004</u> .		
2b)	This action is non-final.		orito io
3) Since this application is in condition for all	lowance except for forma	al matters, prosecution as to tr	ie menis is
closed in accordance with the practice un	der Ex parte Quayle, 193	35 C.D. 11, 453 O.G. 213.	
Disposition of Claims			
4) Claim(s) <u>1-36</u> is/are pending in the applicate 4a) Of the above claim(s) <u>1-9 and 21-36</u> is 5) Claim(s) is/are allowed. 6) Claim(s) <u>10-20</u> is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and the application is a subject to restriction is a subject to restriction.	s/are withdrawn from con		
Application Papers			7
9) The specification is objected to by the Example 1	aminer.	tod to by the Evaminer	
10) The drawing(s) filed on _3 is/are: a) ☐ Applicant may not request that any objection	_ accepted or b)∟_ object	abevance See 37 CFR 1.85(a)	
Applicant may not request that any objection Replacement drawing sheet(s) including the	to the drawing(s) be field in	drawing(s) is objected to. See 37	CFR 1.121(d).
Replacement drawing sheet(s) including the cath or declaration is objected to by the cath or declaration is objected to be a cath or declaration.	the Examiner. Note the a	ttached Office Action or form	PTO-152.
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for for a) All b) Some * c) None of: 1. Certified copies of the priority documents of the priority documents of the priority documents of the certified copies of the application from the International * See the attached detailed Office action for the priority documents of the priority docum	uments have been receiv uments have been receiv ne priority documents hav Bureau (PCT Rule 17.2(a	red. red in Application No re been received in this Nation a)).	nal Stage
- See the attached detailed Office action to	. 4 5 55 55		
Attachment(s) 1) Notice of References Cited (PTO-892)	4) 🔲 I	nterview Summary (PTO-413)	
 1) Notice of References Cited (F10-392) 2) Notice of Draftsperson's Patent Drawing Review (PT0-4) 3) Information Disclosure Statement(s) (PT0-1449 or PT0 Paper No(s)/Mail Date <u>12-24-2003</u>. 	5) 🔲 1	Paper No(s)/Mail Date Notice of Informal Patent Application Other:	(PTO-152)

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DETAILED ACTION

Election/Restrictions

Applicant's election of group II in the reply filed on 9-20-2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

It is noted that the restriction requirement mailed 8-18-2004 did not take into account the preliminary amendment filed 8-16-2004, which adds new claims 21-36. In terms of the elected invention, only claims 10-20 will be examined since newly added claims 24, 28-35 are included in the method claims of non-elected group I, while newly added claims 21-23, 25-27 and 36 are drawn to a third apparatus group, namely group III, which is a subcombination usable together with group II but having separate utility as a device with a second coating on a second conductor, but not necessarily forming a separate layer.

Claims 1-9, 21-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected groups I and III, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9-20-2004.

The disclosure is objected to because of the following informalities:

Applicant needs to complete the "Cross-reference to related patent documents" section of his application found on page 1 of his specification to indicate the serial numbers of the applications applicant is referring to rather than the attorney

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docket reference numbers. Also see the last line of page 26 as well as the top line of page 29 of the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-11, 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Kordis et al. USPN 5,476,495.

Kordis shows and discusses the embedding of spiral wound conductors in a mapping probe catheter 18 lead body that is implanted into the body during procedures of mapping and ablation. For example, figures 31 –33 show a unitary wall member 96 of the mapping probe 18 having an inner portion 106 forming a lumen108. An inner layer is shown having at least one conductor 110 as well as an outer layer 112 having at least one conductor, both layers being within the unitary wall. At least connector 44 communicates with a plethora of electrodes on the basket member 24. The mapping probe can be much smaller than 34 French (column 6 lines 46-50) and is made of materials Pebax and Teflon that can be used as extrusion materials.

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Claims 10-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Diaz USPN 5,824,026.

Diaz teaches a catheter with a unitary wall extending from the inner lumen to the wall 17, comprising an inner portion 32 that forms a lumen, an inner layer 34 and/or 42, an outer layer 36 and at least one electrode (see stripped region 20) that is inherently connected to a stimulus for depolarizing the heart (namely a defibrillator –see column 6 lines25-35) through some sort of connector (be it a welded connection or pin). The inner layer 34and/or 42 may additionally be connected to the sensor electrodes 22, 24, 26 for a total of 6 electrodes.

Polyurethane which is considered an extrusion material (i.e. material that can be used in extrusion) is used in the outer covering 17 and therefore the unitary wall is comprised of an extrusion material. For the defibrillator embodiment the the catheter is sized well below a 34 french diameter – column 6 lines 32-35.

Claims 10 –12, 14-17, 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Brownlee USPN 5,772,693.

Brownlee shows a catheter construction (see figure 20) with a unitary wall having an inner portion (see inner most coil 56 and inner most sheath 54) with an inner layer conductor (second inner most coil 56) and outer layer(third inner most or outer most coil) within the unitary wall. The catheter is formed with extrusion material on each of the coils followed by insertion and heat setting to achieve its shape. See column 5 lines 10-26 and column 12 lines 15-25 for instance.

Connectors 914) are formed at the proximal end and in the embodiment of figure

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13, 5 electrodes 22, 24, 80, 38 and 41 are shown. The device is connect to a pacemaker to provide a stimulus for pacing the heart.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 13 and 18are rejected under 35 U.S.C. 103(a) as being unpatentable over Brownlee USPN 5,772693. While Brownlee is silent to the cross-sectional size of the lead a size 34 french is very large and to have manufacture the Brownlee lead smaller than such would have been apparent to those of ordinary skill in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W Bockelman whose telephone number is (571) 272-4941. The examiner can normally be reached on Monday - Friday 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272 -4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWB

November 26, 2004

MARK BOCKELMAN MARK BOCKELMAN DOMINER